

510(k) SUMMARY
Lanx Spinal Fixation System

SEP 10 2012

Submitter Information

Name and Address: Lanx, Inc.
310 Interlocken Parkway, Suite 120
Broomfield, CO 80021
(303) 443-7500

Contact Person: William Sandul

Date Prepared: September 6, 2012

Device Identification

Proprietary Name: Lanx Spinal Fixation System

Common Name: Spinal Fixation System

Classification: Pedicle Screw Spinal System and/or Spinal Interlaminar Fixation
Orthosis (per 21 CFR 888.3050 and/or 888.3070)

Predicate Device Information

K103091 Lanx Spinous Process Plate

K073278 Nuvasive Affix Spinous Process Plating System

K103205 Alphatec Spine BridgePoint Spinous Process Fixation System

K100354 OsteoMed PrimaLOK Interspinous Fusion System

K102195 Globus SP-Fix Spinous Process Fixation Plate

K102020 SpineFrontier InSpan Interspinous Fixation System

Intended Use / Indications for Use

The Lanx Spinal Fixation System (SFS) is intended to be used to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the thoracic, lumbar and/or sacral spine. The System is intended for use with autograft or allograft.

The Lanx Spinal Fixation System is intended for posterior, non-cervical (T1-S2/ilium) pedicle and non-pedicle spinal fixation, to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following instabilities or deformities: degenerative disc disease (DDD, defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis;

trauma (i.e. fracture or dislocation); spinal stenosis; deformities or curvatures (i.e. scoliosis, kyphosis and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

The Lanx Spinous Process Fusion Plate (SPFP) is a posterior, non-pedicle supplemental fixation device, intended for use at a single level in the non-cervical spine (T1-S1). It is intended for plate fixation/attachment to spinous processes for the purpose of achieving supplemental fusion in the following conditions: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); and/or tumor. The Lanx SPFP is intended for use with bone graft material, not intended for stand-alone use.

Device Description & Technological Characteristics

The purpose of this 510(k) submission is to add an adjustable-length spinous process fusion plate to the Lanx Spinal Fixation System. The modified system has the same intended use and fundamental scientific technology as the previously-cleared system.

The Lanx Spinal Fixation System consists of various screws, hooks, rods, plates, connectors, etc. that are used to build a construct to provide supplemental stabilization of spinal segments to support fusion. The system components can be assembled in a variety of configurations, allowing the surgeon to tailor the construct to the particular needs of the patient.

The Lanx Spinal Fixation System implants are fabricated from medical grade titanium, titanium alloy and/or cobalt chrome alloy per ASTM F67, ASTM F1580, ASTM F136 and ASTM F1537. Titanium and cobalt chrome components may be used together within the same construct. These components should never be used with stainless steel implant components.

Performance Data

Performance testing and engineering analysis was performed and submitted to characterize the new components added to the system. Static and dynamic axial compression and static torsion tests, in accordance with ASTM F1717, were performed on the modified and predicate systems, and the results compared. The modified device functioned as intended and the observed test results demonstrate substantial equivalence to the predicate device.

To establish the mechanical characteristics of the coating, mechanical tests were conducted in accordance with ASTM 1147 (tensile), ASTM F1044 (shear), ASTM F1160 (shear fatigue) and ASTM F1978 (abrasion). The mechanical characteristics of the coating were demonstrated to be substantially equivalent to the predicate coating.

Substantial Equivalence

The modified Lanx Spinal Fixation System has the same intended use and indications for use, and the same or very similar technological characteristics and principles of operation as the predicate system. The minor differences in the new components do not raise any new issues of safety or effectiveness. Testing also demonstrated comparable properties to the previously cleared Lanx Spinal Fixation System. Thus, the modified Lanx Spinal Fixation System is substantially equivalent to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room—WO66-G609
Silver Spring, MD 20993-0002

Lanx, Incorporated
% Mr. Will Sandul
Director of Engineering
310 Interlocken Parkway, Suite 120
Broomfield, Colorado 80021

SEP 10 2012

Re: K121316
Trade/Device Name: Lanx Spinal Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, KWP, MNH, MNI
Dated: August 24, 2012
Received: August 29, 2012

Dear Mr. Sandul:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

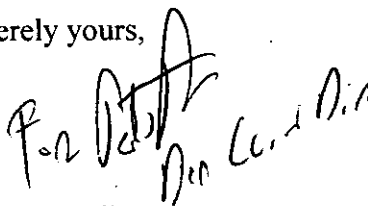
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", is written over the typed name and title.

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K121316

Device Name:

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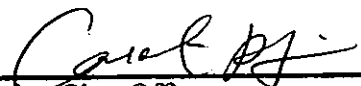
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

Page 1 of 1

510(k) Number K121316